IFW

Attorney Docket No.: 6459.500-US PATENT

OIPE JC10 SEP 01 2004 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Thim et al.

Serial No.: 10/685,368 Group Art Unit: 1641

Filed: October 14, 2003 Examiner: To be assigned

For: GLP-2 Compounds, Formulations and Uses Thereof

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence comprising:

1. Supplemental Information Disclosure Statement
2. Form PTO-1449
3. Copy of References

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on **August 30, 2004**

Csaba Attila Szakolczai
(name of person mailing paper)

Csaba Attila Szakolczai
(signature of person mailing paper)

OIPE JC10 3C
SEP 01 2004
PATENT & TRADEMARK OFFICE

Attorney Docket No.: 6459.500-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Thim et al.

Application No.: 10/685,368 Group Art Unit: 1641

Filed: October 14, 2003 Examiner: To be assigned

For: GLP-2 Compounds, Formulations and Uses Thereof

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no material references other than those listed exist or that a search has been conducted.

The references are listed in Form PTO-1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

1. U.S. Patent no. 5,470,582
2. U.S. Patent no. 5,512,549
3. U.S. Patent no. 5,624,894
4. U.S. Patent no. 5,789,379
5. U.S. Patent no. 5,869,602
6. WO 91/11457 A1
7. WO 95/07931 A1
8. WO 96/32414 A1
9. WO 97/39031 A1
10. WO 97/31943 A1
11. WO 98/08872 A1
12. Clodfelter et al., (1998) Pharmaceutical Res. 15(2):254-262
13. U.S. Patent no. 5,834,428
14. U.S. Patent no. 5,912,229
15. U.S. Patent no. 5,952,301
16. U.S. Patent no. 5,990,077
17. U.S. Patent no. 5,994,500

18. U.S. Patent no. 6,051,557
19. U.S. Patent no. 6,184,201 B1
20. U.S. Patent no. 6,297,214 B1
21. U.S. Patent no. 6,489,295
22. U.S. Patent no. 6,586,399 B1
23. U.S. Patent Application Publication no. US 2001/0021767 A1
24. U.S. Patent Application Publication no. US 2001/0027180 A1
25. U.S. Patent Application Publication no. US 2003/0040478 A1
26. U.S. Patent Application Publication no. US 2003/0109449 A1
27. U.S. Patent Application Publication no. US 2003/0158101 A1
28. U.S. Patent Application Publication no. US 2003/0162703 A1
29. WO 98/25644 A1
30. WO 98/52600 A1
31. WO 99/43361 A1
32. WO 99/58144 A1
33. WO 01/41779 A2
34. WO 01/49314 A2 and A3
35. EP 0891378 B1
36. Shennan et al., Molecular and Cellular Endocrinology; Vol. 67; 1989; pp. 93-9
37. Watanabe et al., Biochemical and Biophysical Research Communications; Vol. 152, No. 3; May 16, 1988; pp. 1038-1044
38. Lund et al., Digestion; Nov.-Dec. 1993; pp. 371-373
39. Orskov et al., Diabetologia; Vol. 30; 1987; pp. 874-881
40. Orskov et al., FEBS Letters; Vol. 247 No. 2; Apr. 1989; pp. 193-196
41. George et al., FEBS Letters; Vol. 192, No. 2; 1985; pp. 275-278
42. Hoosein et al., FEBS Letters; Vol. 178, No. 1; Dec. 1984; pp. 83-86
43. Buhl et al., The Journal of Biological Chemistry; Vol. 263, No. 18; Jun. 25, 1998; pp. 8621-8624
44. Lee et al., The Journal of Biological Chemistry; Vol. 267, No. 15; May 1992; pp. 10705-10708
45. Orskov et al., Scand. J. Clin. Lab. Invest; Vol. 47, No. 2; Apr. 1987; pp. 165-174
46. Barragan et al., American Journal of Physiology; Vol. 266, No. 3, Part 1; Mar. 1994; pp. E459-66
47. Brubaker et al., Endocrinology; Vol. 128, No. 6; 1991; pp. 3175-3182
48. Calvo et al., J. Neurochemistry.; Vol. 64, No. 1; Jan. 1995; pp. 299-306
49. Drucker, Pancreas; Vol. 5, No. 4; 1990; pp. 484-488
50. Mojsov et al., The Journal of Biological Chemistry; Vol. 261, No. 25; Sep. 5, 1986; pp. 11880-11889
51. Orskov et al., Endocrinology; Vol. 119, No. 4; 1986; pp. 1467-1475
52. Madsen et al., Endocrinology, Vol. 133, No. 5, pages 2022-2030 (1993)
53. Siegel et al., Reg. Peptides, Vol. 79, pages 93-102 (1999)
54. Gallwitz et al., Reg. Peptides, Vol. 86, pages 103-111 (2000)
55. WO 98/03547
56. Turton et al., Nature, Vol. 379, pages 69-71 (1996)
57. Flint et al., J. Clin. Invest., Vol. 101, No. 3, pages 515-520 (1998)
58. Gutzwiller et al., Gut, Vol. 44, pages 81-86 (1999)
59. Naslund et al., Int. J. Of Obesity, Vol. 23, pages 304-311 (1999)
60. Sorensen et al., Int. J. Of Obesity, Vol. 27, pages 450-456 (2003)
61. WO 02/066062 A2 & A3

62. Drucker et al., Nature Biotechnology, Vol. 15, pages 673-677 (1997)
63. U.S. Patent No. 5,990,077
64. Nishi et al., Mol. Endocrinology, Vol. 4, pages 1192-1198 (1990)
65. Mentlein et al., Eur. J. Biochem., Vol 214, pages 829-835 (1993)
66. US 08/631,273
67. Peninsula Laboratories, Inc. Catalog, 1993-1994
68. Demuth et al., Chapter 1 in Dipeptidy Peptidase IV (CD26) in Metabolism and the Immune Response, pages 1-35, (Springer, R.G. Landes Co., Austin, TX) (1995)
69. Bongers et al., Biochimica et Biophysica Acta, Vol. 1122, pages 147-153 (1992)
70. Gallwitz et al., Eur. J. Biochem., Vol. 225, pages 1151-1156 (1994)
71. Deacon et al., Diabetes, Vol. 44, pages 1126-1131 (1995)
72. Kieffer et al., Endocrinology, Vol. 136, No. 8, pages 3585-3596 (1995)
73. CA Application No. 2,137,206 to Eli Lilly
74. Drucker et al., Proc. Natl. Acad. Sci. USA, Vol. 93, pages 7911-7916 (1996)
75. Drucker et al., Intestinal Growth Factors, pages G1252-1262
76. Lund et al., Digestion, Vol. 46, Supplement 2, pages 66-73 (1990)
77. Ehrlich et al., Regulation of Proglucagon Gene Expression, pages E662-671
78. Orskov et al., Abstract P6
79. U.S. Patent Application Publication No. 2001/0016643 A1
80. U.S. Patent Application Publication No. 2002/0025933 A1
81. U.S. Patent Application Serial No. 10/730,215
82. Tang-Christiansen et al., Nature Medicine, Vol. 6 (7), pp. 802-7 (July 2000)
83. Substantive Arguments to Date from Opposition to European Patent 0 891 378

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the undersigned if there are any questions concerning this paper or the attached references.

The information disclosure statement submitted herewith is being filed **within** three months of the filing date of a national application or date of entry into the national stage of an international application or **before** the mailing date of a first Office action on the merits, or **before** the mailing date of a first Office action after the filing of a request for continued examination. Therefore, no fee is due. However, please charge any fees should they be required, to Novo Nordisk Pharmaceuticals, Inc. Deposit Account No. 14-1447.

Respectfully submitted,

Date: August 30, 2004

Len S. Smith, Reg. No. 43,139
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650
PATENT TRADEMARK OFFICE

OIPE SEP 01 2004 PATENT & TRADEMARK OFFICE

FORM PTO-1449 (Rev. 7-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 6459.500-US	Serial No. 10/685,368
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Thim et al.	
	(Use several sheets if necessary)	Filing Date October 14, 2003	Group 1641

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,470,582	11/28/95	Supersaxo et al.	424	489	
		5,512,549	04/30/96	Chen et al.	514	12	
		5,624,894	04/29/97	Bodor	514	2	
		5,789,379	08/04/98	Drucker et al.	514	12	
		5,869,602	02/09/99	Jonassen et al.	530	308	
		5,834,428	11/10/98	Drucker	514	12	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
		WO 91/11457 A1	08/08/91	PCT				
		WO 95/07931 A1	03/23/95	PCT				
		WO 96/32414 A1	10/17/96	PCT				
		WO 97/39031 A1	10/23/97	PCT				
		WO 97/31943 A1	09/04/97	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Clodfelter et al., Pharmaceutical Res. 15(2): 254-262 (1998)
			Shennan et al., Molecular and Cellular Endocrinology: Vol. 67; pp. 93-9 (1989)
			Watanabe et al., Biochem and Biophys Res. Com, Vol. 152 (3); pp. 1038-44 (May 16, 1988)
			Lund et al., Digestion; pp. 371-73 (Nov-Dec. 1993)
			Orskov et al., Diabetologia, Vol. 30; pp. 874-81 (1987)
			Orskov et al., FEBS Letters, Vol. 247 (2); pp. 193-96 (Apr. 1989)
			George et al., FEBS Letters, Vol. 192 (2); pp. 275-78 (1985)
			Hoosein et al., FEBS Letters, Vol. 178 (1); pp. 83-6 (Dec. 1984)
			Buhl et al., Journ of Biol Chem, Vol. 263 (18); pp. 8621-24 (June 25, 1998)
			Lee et al., Journ of Biol Chem, Vol. 267 (15); pp. 10705-708 (May, 1992)
			Orskov et al., Scand J. Clin. Lab. Invest, Vol. 47 (2); pp. 165-174 (Apr. 1987)
			Barragan et al., Am. J. of Physiol, Vol. 266 (3 Part 1); pp. E459-66 (Mar. 1994)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 6459.500-US	Serial No. 10/685,368
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Thim et al.	
	(Use several sheets if necessary)	Filing Date October 14, 2003	Group 1641

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,912,229	06/15/99	Thim et al.	514	12	
		5,952,301	09/14/99	Drucker	514	12	
		5,990,077	11/23/99	Drucker	514	2	
		5,994,500	11/30/99	Drucker et al.	530	324	
		6,051,557	04/18/00	Drucker	514	12	
		6,184,201 B1	02/06/01	Drucker et al.	514	12	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
		WO 98/08872 A1	03/05/98	PCT				
		WO 98/25644 A1	06/18/98	PCT				
		WO 98/52600 A1	11/26/98	PCT				
		WO 99/43361 A1	09/02/99	PCT				
		WO 99/58144 A1	11/18/99	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Brubaker et al., Endocrin., Vol. 128 (6); pp. 3175-82 (1991)
			Calvo et al., J. Neurochem, Vol. 64 (1); pp. 299-306 (Jan. 1995)
			Drucker, Pancreas, Vol. 5 (4); pp. 484-88 (1990)
			Mojsov et al., Journ of Biol. Chem., Vol. 261 (25); pp. 11880-89 (Sept. 5, 1986)
			Orskov et al., Endocrin., Vol. 119 (4); pp. 1467-75 (1986)
			Madsen et al., Endocrin., Vol. 133 (5); pp. 2022-30 (1993)
			Siegel et al., Reg. Peptides, Vol. 79; pp. 93-102 (1999)
			Gallwitz et al., Reg. Peptides, Vol. 86; pp. 103-11 (2000)
			Turton et al., Nature, Vol. 379; pp. 69-71 (1996)
			Flint et al., J. Clin. Invest., Vol. 101 (3); pp. 515-20 (1998)
			Gutzwiller et al., Gut, Vol. 44; pp. 81-6 (1999)
			Naslund et al., Int. J. of Obesity, Vol. 23; pp. 304-11 (1999)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 6459.500-US	Serial No. 10/685,368
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Thim et al.	
	(Use several sheets if necessary)	Filing Date October 14, 2003	Group 1641

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6,297,214 B1	10/02/01	Drucker	514	12	
		6,489,295 B1	12/03/02	Drucker et al.	514	12	
		6,586,399 B1	07/01/03	Drucker	514	12	
		5,990,077	11/23/99	Drucker	514	2	
		2001/0021767 A1	09/13/01	Drucker et al.	530	320	
		2001/0027180 A1	10/04/01	Isaacs	514	12	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
		WO 01/41779 A2	06/14/01	PCT				
		WO 0149314 A2&A3	07/12/01	PCT				
		EP 0891378 B1	02/27/97	EP				
		WO 98/03547	01/29/98	PCT				
		WO 02/066062 A2&A3	08/29/02	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Sorensen et al., Int. J. of Obesity., Vol. 27; pp. 450-56 (2003)
			Drucker et al., J. Nature Biotech, Vol. 15; pp. 673-77 (1997)
			Nishi et al., Mol. Endocrin., Vol. 4; pp. 1192-98 (1990)
			Mentlein et al., Eur. J. Biochem., Vol. 214; pp. 829-35 (1993)
			Peninsula Laboratories, Inc. Catalog 1993-1994
			Demuth et al., Dipeptidy Peptidase IV (CD26) in Metab. Immune Resp., Chptr 1, pp. 1-35 (Springer, RG Landis Co., Austin TX) (1995)
			Bongers et al., Biochim et Biophys. Acta, Vol. 1122; pp. 147-53 (1992)
			Gallwitz et al., Eur. J. Biochem, Vol. 225; pp. 1151-56 (1994)
			Deacon et al., Diabetes, Vol. 44; pp. 1126-31 (1995)
			Kieffer et al., Endocrin., Vol. 136 (8); pp. 3585-96 (1995)
			Drucker et al., Proc. Natl. Acad. Sci. USA, Vol. 93; pp. 7911-7916 (1996)
			Drucker et al., , Intestinal Growth Factors; pp. G1252-62

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 6459.500-US	Serial No. 10/685,368
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Thim et al.	
	(Use several sheets if necessary)	Filing Date October 14, 2003	Group 1641

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		2003/0040478 A1	02/27/03	Drucker et al.	514	12	
		2003/0109449 A1	06/12/03	Drucker et al.	514	12	
		2003/0158101 A1	08/21/03	Drucker	514	12	
		2003/0162703 A1	08/28/03	Drucker et al.	514	12	
		08/631,273					
		2001/0016643 A1	08/23/01	Jonassen et al.	530	300	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
		CA 2,137, 206	12/02/94	CA				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Lund et al., Digestion., Vol. 46 (suppl. 2); pp. 66-73 (1990)
			Ehrlich et al., Reg. of Proglucagon Gene Express.; pp. E662-71
			Orskov et al., Abstract P6
			Tang-Christiansen et al., Nature Medicine, Vol. 6 (7), pp. 802-7 (July 2000)
			Substantive Arguments to Date from Opposition to European Patent 0 891 378

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 6459.500-US	Serial No. 10/685,368
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Thim et al.	
	(Use several sheets if necessary)	Filing Date October 14, 2003	Group 1641

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		2002/0025933 A1	02/28/02	Knudsen et al.	514	12	
		2004-0127418-A1	07/01/04	Knudsen et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.